AUG - 7 2003

K031586

Appendix D — 510(k) Summary

Trade Name: CorRestore™ Patch System, new suture supplier

Common Name: Intracardiac Patch or Pledget

Establishment Information:
Somanetics Corporation
1653 East Maple Road
Troy, MI 48083
Phone: (248) 689-3050
Fax: (248) 689-4272

Contact Person: Ronald A. Widman, Vice President of Medical Affairs

Classification: Class II, Panel 74 DXZ

Product Description:
The CorRestore Patch is an oval tissue patch made from glutaraldehyde fixed bovine pericardium. It is intended to be used as an intracardiac patch for cardiac reconstruction and repair. It is identical to other marketed bovine pericardium patches except that it incorporates an integral suture bolster (also made of fixed bovine pericardium) in the shape of an oval ring and is packaged with accessories needed for cardiac repair and reconstruction. The CorRestore Patch comes as a kit including a patch and suture strip (1.4 x 16 cm), both manufactured from processed bovine pericardium. Optionally included is a set of various sutures needed for implantation. To assist the surgeon in determining the appropriate size, a separate disposable sizer kit is offered.

The CorRestore Patch comes in three sizes:

(Predicate) Without Sutures	(Predicate) W/ Ethicon Sutures	(New) W/ Genzyme Sutures	Product
1.5P2	1.5P2S	1.5P2SG	1.5 x 2 cm* CorRestore Patch
2P3	2P3S	2P3SG	2 x 3 cm* CorRestore Patch
3P4	3P4S	3P4SG	3 x 4 cm* CorRestore Patch

*Sizes refer to inside dimensions of suture ring; actual sizes are larger

Accessory:

CRPS	CorRestore Patch Sizer Set

Substantial Equivalence:
The CorRestore patch is equivalent in indications for use, size, shape, material, manufacturing processes, sterilization, packaging, instructions and intended use to the predicate CorRestore Patch System, K011487. The only change is the addition of a new suture supplier, Genzyme. Sutures are packaged in the same way with labeling appropriate for their premarket notification status, the same as the predicate. The packaging prevents liquid sterilant from contacting the sutures. Therefore, the CorRestore Patch is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2003

Mr. Ronald A. Widman
Vice President of Medical Affairs
Samanetics Corporation
1653 East Maple Road
Troy, MI 48083

Re: K031586
Trade Name: CoreRestore™ Patch System
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch or Pledget
Regulatory Class: Class II (two)
Product Code: DXZ
Dated: May 19, 2003
Received: May 21, 2003

Dear Mr. Widman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

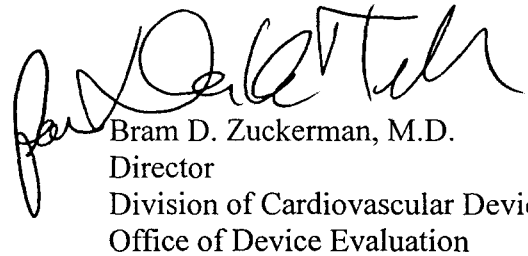
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K031586

Device Name: CorRestore™ Patch System Processed Bovine Pericardial Patch

Indications For Use:
The CorRestore patch is intended for use as an intracardiac patch for cardiac reconstruction and repair.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031586

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)